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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,857	02/25/2002	Jan Weber	01-264US 6210	
38356 BROOKS, CA	7590 10/20/200 MERON & HUEBSCH		EXAM	IINER
1221 NICOLL	ET AVENUE, SUITE		BUI,	VY Q
MINNEAPOLIS, MN 55403		,	ART UNIT	PAPER NUMBER
			3773	
			MAIL DATE	DELIVERY MODE
			10/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET		
10084857	2/25/2002	WEBER, JAN	01-264US  EXAMINER		
BBOOKS CAMEBON	9 HUEDCOU DU O	<i>,</i>			
BROOKS, CAMERON 1221 NICOLLET AVEN MINNEAPOUS MN 5	NUE , SUITE 500	•		Vy Q Bui	
MINNEAPOLIS, MN 55403			ART UNIT	PAPER	
•		•	3773	20080325	
		· .	*		

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner for Patents** 

Dear Sir:

Attached is the "Supplemental Examiner's Answer" with TC Director's signature for your reference to replace the defective "Supplemental Examiner's Answer" (paper 10/17/2006) as indicated by the "Board of Patent Appeals and Interferences":

Thank you,

∕Vy Q. Bui/ Primary Examiner, Art Unit 3773 Application/Control Number: 10/084,857

Art Unit: 3773

# **DETAILED ACTION**

# Supplemental Examiner's Answer

In response to the "Order Returning Undocketed Appeal To Examiner" (paper 7/20/2007) from the "Board of Patent Appeals and Interferences", the previous paper (10/17/2006) has been vacated and has been substituted by this "Supplemental Examiner's Answer" as ordered by the "Board of Patent Appeals and Interferences".

The applicant <u>did not</u> provide any argument regarding the rejections under 35 U.S.C. 103(a) after "Non Final Rejection" (paper 5/16/2005) and after "Final Rejection" (paper 1/1/23/2005). However, after "Advisory Action" (paper 1/31/2006), the applicant's Attorney has raised many new arguments.

In the "Appeal Brief" (paper 3/24/2006), the applicant argued about the rejections under 35 U.S.C. 103(a) for the first time. The new arguments raised in the "Appeal Brief" (3/24/2006) after "Advisory Action" (1/31/2006) were addressed in the "Examiner's Answer" (paper 6/15/2006).

Again, the applicant raised <u>new arguments</u> in the "Appellant's Reply Brief" (07/10/2006). However, the "Appellant's Reply Brief" has been considered, entered and responded as presented below.

The application is forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

# Response to Arguments

Applicant's arguments filed 7/10/2006 have been fully considered but they are not persuasive.

I. Response to applicant's argument regarding 102(e) rejection as anticipated by Garibaldi-6,364,823:

<u>Claim 1:</u> "(Previously presented) A vascular treatment device, comprising: a stent formed with a magnetically susceptible material having a magnetic susceptibility that decreases within a preselected temperature range."

As to claim 1, Garibaldi-'823 (col. 8, lines 57-61) teaches a stent formed by magnetic patches 120, which are made from a highly flexible material such as silicone or plyurethane or a bioadsorbalbe material (col. 7, line 65 to col. 8, line 2), which stent can be adsorbable overtime by the body (col. 8, lines 59-61) and hoop 122 made of nitinol or some other structure or construction (col. 8, lines 6-9) and a magnetic responsive material (col. 8, lines 12-14).

It is not deniable that Garibaldi-'823 teaches a stent including magnet material for easy manipulation when the stent is deployed inside a patient body.

It is not deniable that a magnetic material, inherently must has an associated Curie temperature (Curie temperature T is defined as a temperature of a ferromagnetic material M, which above the temperature T, the ferromagnetic material M will lose its ferromagnetism, see Garibaldi-'823: col. 13, lines 18-20).

Because Garibaldi-'823 stent has a magnetic material, therefore, at a temperature range of about the Curie temperature of the magnetic material, inherently, Garibaldi-'823 stent must decrease its magnetic susceptibility as recited in claim 1.

Notice that claim 1 essentially does not require anything further than a stent formed with a magnetically susceptible material.

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Art Unit: 3773

Claim 20: "(Original) A vascular treatment system, comprising:

an electromagnetic field generator; and

a medical device deliverable to a treatment site and including a magnetically susceptible material being magnetically susceptible to an electromagnetic field generated by the generator and having a Curie temperature in a pre-selected temperature range, such that the implantable device heats to a temperature sufficient to treat the treatment site when the electromagnetic field is applied."

As to independent claim 20, the applicant admitted that heat is generated when a magnetic field is applied to the Garibaldi-'823 stent formed of patches 120, but argued that the generated heat is **not sufficient** to treat a treatment site of a patient.

However, independent claim 20 **does not** specify how much heat is sufficient and how much heat is insufficient. Therefore, it is impossible for one of ordinary skill in the art to recognize the difference between the present claimed invention and the Garibaldi-'823 device.

II. Response to applicant's argument regarding 103(a) rejection of claims 8, 11, 26 and 29 as obvious over Garibaldi-6,364,823:

As to claims 8, 11, 26 and 29, the applicant (Appellant's Reply Brief, page 16, paragraph 3) argued that Gadolinium is a malleable and ductile material that cannot possess the proper elastic properties to provide the function required by hoop 122 of Nitinol, for example, as disclosed by Garibaldi-'823.

However, it is well known that a Gadolinium is as elastic as nitinol because they have very similar modulus of elasticity. Indeed, the modulus of Gadolinium is about 75.8 Gpa (see page 1 of 4 of attachment) in comparison with that of Nitinol (about 75Gpa in austenite state or super-elastic state; see page 2 of 4 of attachment). Notice that in a martensite state, Nitinol is

more ductile because the modulus of elasticity of Nitinol is only about 40 Gpa (page 2 of 4 of attachment), but still more elastic than lead, which has a modulus of elasticity of about 13.8 Gpa (see page 4 of 4 of attachment).

It is convincing that one can substitute a Gadolinium for an austenitic Nitinol because both the materials have equivalent modulus of elasticity.

III. Response to applicant's argument regarding 103(a) rejection of claim 12 as obvious over Garibaldi-6,364,823:

As to claim 12, the applicant (Appellant's Reply Brief, page 16, paragraph 3) argued that it is not obvious to use ferrite oxide (FeO) or chromium oxide (CrO) in place of gadolinium as a magnetically susceptible material.

Because gadolinium and ferrite oxide and chromium oxide are well-known materials. It would be within level of one of ordinary skill in the art to use a ferrite oxide or a chromium oxide in a device such as Garibaldi-'823 device as long as a substitute of a ferrite oxide or a chromium oxide does not destroy the function of the device.

IV. Response to applicant's argument regarding 103(a) rejection of claim 28 as obvious over Garibaldi-6,364,823 and Doscher-6,786,904:

As to claim 28, the applicant (Appellant's Reply Brief, page 19, paragraphs 2-3) argued that there is no motivation to combine Garibaldi-'823 and Doscher-'904.

Notice that Doscher-'904 teaches using a magnetic field as disclosed in US Pat.
6,238,421 to generate heat to a partial coating of a magnetically susceptible material of a stent which is implanted to treat an inner surface of a blood vessel of a patient more effectively
(Doscher-'904: col. 10, lines 59-67). It would have been obvious to one of ordinary skill in the

art at the time of the invention to provide a Doscher-'904 stent partially coated for an effective treatment of the inner surface of the patient blood vessel.

Further, Garibaldi-'823 discloses a stent including a magnetically susceptible material implanted in a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a Garibaldi-'823 having a partial coat of a susceptible material so that one can effectively direct the heat source generated by a magnetic field to an inner surface of a blood vessel.

V. Response to applicant's argument regarding 103(a) rejection of claims 44, 45, 48 and 49 as obvious over Garibaldi-6,364,823:

Garibaldi-'823 (col. 8, lines 2-15; Fig. 10-12) discloses hoop 122 of nitinol and outer layer/coating having iron particles as a magnet material. Garibaldi-'823 discloses a layer/coating of iron particles. Garibaldi-'823 does not discloses the layer/coating is sintered or painted. However, the manner of making the layer/coating will be given more patentability in a method claim.

VI. Response to applicant's argument regarding 103(a) rejection of claims 42 and 46 as obvious over Garibaldi-6,364,823:

The rejection of independent claims 1 and 20 are proper as indicated above. Therefore, the rejection 103(a) of the claims 42 and 46 are also appropriate.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Attachment: 4 reference pages regarding "General Information on element Gadolinium and

Lead".

Vy Q. Bui

Primary Examiner, Art Unit 3773

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

KAREN M. YOUNG DIRECTOR

**TECHNOLOGY CENTER 3700** 



### **Materials Home**

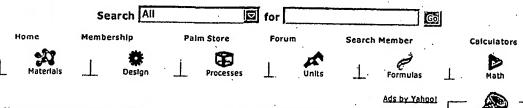
Element Information: Gadolinium
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# Pure Elements Periodic Table Element List by Name by Symbol by Atomic Number by Atomic Weight Element Information Resources Bibliography

Bibliography
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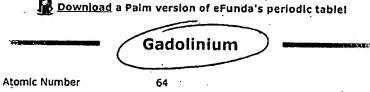
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64 Atomic Atomic

157.25

Gd Atomic Weight 157.25 Electron Config.

2-2-6-2-6-10-2-6-10-7-2-6-1-0-2

Electron configuration order: 1s-2s-2p-3s-3p-3d-4s-4p-4d-4f-5s-5p-5d-5f-6s-6p-6d-7s

	Mechanical Properties					
	riccianical Properties		Phase	Temp. (K)	Pressure (Pa)	
	Density	7900 kg/m <sup>3</sup>	Solid	298.15	0	
×	Modulus of Elasticity	75.842 GPa	Solid	0	·	
•	Poisson Ratio	0.26	Solid			
	Thermal Expansion Coefficient	$9.000 \times 10^{-6} / K$	Solid	298.15		
	Electrical Properties			Co	nditions	
				Temp. (i	K) Note	
	Electrical Resistivity	$1.405 \times 10^{-6} \Omega$ -m		298.15		
	Thermal Properties			Condition	ns	
	······································		Temp. (	<b>K)</b> 1	Pressure (Pa)	
	Melting Temperature	1587.15 K		•	101325	
	Boiling Temperature	3537.15 K			101325	
	Critical Temperature	8670 K				
	Fusion Enthalpy	62.4 J/g	0	•	101325	
	Heat Capacity	236 J/kg-K	298.15		100000	
	Thermal Conductivity	10.5 W/m-K	300 more	l	101325	

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### Melt Practice

Nitinol is a family of alloys which are comprised of near equiatomic percentages of nickel and titanium. A few variants of Nitinol also include small amounts of a third element that is used to alter certain properties. Nitinol exhibits a thermoelastic martensitic transformation. This transformation is responsible for either shape memory or superelasticity being exhibited by the alloy. Following deformation below the transformation range, the ability called shape memory allows recovery of a predetermined shape upon heating above the transformation range. Superelasticity is the ability to recover a shape upon removal of an applied stress over a narrow range of deformation temperatures. The strain recovered with shape memory or superelasticity provides nearly ten times the elastic springback of other alloys such as stainless steel.

# **Typical Chemistry**

	F	FWM NiTi #1	 FWM Avg.
Nickel	. 5	64.5-57.0 wt. %	56.0 wt %
Carbon	O	0.050 wt % Max.	0.033 wt % Max.
Oxygen	. 0	0.050 wt % Max.	0.028 wt % Max.
Hydrogen	. 0	0.005 wt % Max.	 0.0025 wt % Max.
Titanium	· · •	Balance	Balance

In addition to FWM's NiTi #1 (High Nickel Superelastic Binary), requirements for a variety of binary and ternary chemistries can be made available.

# **Physical Properties**

These values are typical for FWM NiTi#1

		Austenite	Martensite
	Density	6.4 <u>5 g/cm</u> 3	6.45 g/cm 3
*	Modulus of Elasticity	(15GPa )	40GPa
•	Electrical Resistivity	82X10 -6 ohm-cm	76x10 -6 ohm-cm
	Magnetic Susceptibility	3.7x10 -6 emu/g →	2.4x10 -6 emu/g
	Coefficient of Thermal Expansion	11x10 -6 /°C	6.6x10 -6 /°C

### **Transformation Properties.**

Because shape memory and superelasticity are very temperature dependent, there are a number of thermal points of interest that deserve discussion in order to gain an understanding of the material. This paper will discuss two of these points: the fully annealed austenitic peak and the active austenitic finish temperatures. The fully annealed austenitic peak (A p ) is a temperature that FWM uses in order to classify the types of Nitinol. Several companies will make use of different points, but the intent of the measurements are the same. The A p is the point that the fully annealed Nitinol has the highest rate of transformation from Martensite to Austenite. The active austenitic finish temperature (Active A f ) is a finished material property that is measured after heat treatment. This is the temperature at which the material has completely transformed to Austenite, which means that at and above this temperature the material will have completed its shape memory transformation or will display its superelastic characteristics. For a more detailed discussion of thermal properties and the effect that they may have on your finished product, please feel free to contact FWM.

Fully Annealed Austenitic Peak (A p ) by Differential Scanning

-25 to -5 °C

Calorimeter

Active Austenitic Finish (A f) by bend and free recovery

10 to 20 °C

# **Product Forms**

Round Wire: Size Range .0005" up to .250" Flat Wire: Minimum thickness down to .0003"

Strands and Cables. Nitinol is available in all of our standard strand configurations.

DFT (drawn filled tubing): Please call FWM regarding your DFT needs.

Turkshead and Specialty Shapes: FWM has recently added the capability to manufacture your

square, rectangle or other shaped cross-sectional wire needs.

# **Surface Finishes**

Light Oxide: (LO) Gold to Brown color - diamond drawn surface Dark Oxide: (DK) Grey to Black color - diamond drawn surface Black Oxide: (BLK) Shiny Black color - diamond drawn surface

Etch: (E) chemical removal of oxide layer - will retain smooth surface

Pickled: (P) chemical removal of oxide layer along with a slight amount of base metal - surface

will have a rough texture

Etched and Mechanically Polished: (EMP) Chemical removal of oxide layer followed by mechanical polish - surface will have stainless steel appearance (although at >40x magnification, micro scratches will be present)

### Mechanical Properties (at 21 +/- 3°C)

Two critical characteristics unique to Nitinol in the austenitic phase are the loading plateau and the unloading plateau. The loading plateau stress is the stress level at which material at a specific temperature above A f will force Austenite phase into Martensite. This produces an almost constant stress level over a relatively large range of strain, up to about 8%. The unloading plateau stress is the stress level at which the Martensite will return to the Austenitic phase.



# Materials Home

 Pure Elements Periodic Table Element List by Name by Symbol by Atomic Number by Atomic Weight

Bibliography

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Temp. (K)

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**Element Information Sheet Metal Fabrication** Resources

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Phase

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**Mechanical Properties** 

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Lead

Atomic Number 82 82 Pb Atomic Weight 207.2 207.2 Electron Config. 2-2-6-2-6-10-2-6-10-14-2-6-10-0-2-2

Electron configuration order: 1s-2s-2p-3s-3p-3d-4s-4p-4d-4f-5s-5p-5d-5f-6s-6p-6d-7s

			· citipi (it)	11033016 (14)
Density	11300 kg/m <sup>3</sup>	Solid	298.15	. 0
Modulus of Elasticity	13.79 GPa	Solid	0	
Poisson Ratio	0.44	Solid		•
Thermal Expansion Coefficient	2.890 × 10 <sup>-5</sup> /K	Solid	298.15	
Electrical Properties			Con	ditions
Licetifed Properties		•	Temp. (K	) Note
Electrical Resistivity	$2.065 \times 10^{-7} \Omega$ -m		•	
Thermal Properties			Conditions	
THE THE TOP CITIES		Temp. (K)		Pressure (Pa)
Melting Temperature	600.61 K			101325
Boiling Temperature	2022.15 K			101325
Critical Temperature	5500 K			·
Fusion Enthalpy	23 J/g	0		101325
Vaporization Enthalpy	866.31 J/g	0		101325
Heat Capacity	129 J/kg-K	298.15 more		. 100000
Thermal Conductivity	35.3 W/m-K	300 <u>more</u>	<i>,</i>	101325

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# UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

I've just received these med folders this morning from Factore. These cases

have been in my docker

for a long time.

MAILED

Ex parte JAN WEBER

Application 10/084,857 Technology Center 3700

ORDER RETURNING UNDOCKETED APPEAL TO EXAMIN

Could you please

process these cases This Image File Wrapper (IFW) application was electronically received at the Board of Patent Appeals and Interferences on July 9, 2007. A re revealed that the application is not ready for docketing as an appeal. Accordingly the application is herewith being returned to the Examiner. The matters requiring attention prior to docketing are identified below:

The Examiner's Answer mailed June 15, 2006, contains a new ground of rejection, the proper authoritative signature has not been provided in accordance with the Manual of Patent Examining Procedure (MPEP) § 1207.03 wherein the Technology Center Director's signature must be present. Also, the Examiner fails to include claims 42, 44-46 and 48-491 in the 35 U.S.C. § 103(a) statement of the rejection in the "Grounds of Rejection" section of the Answer (see Answer 4), but responds to Appellants arguments regarding these claims (see Answer 7-8). Clarification on the written record is required.

The Final Rejection, mailed November 23, 2005, fails to list these claims in the 35 U.S.C. § 103(a) rejection (Final Office Action 3).

# Application 10/084,857

Further review has revealed that the Office action dated October 17, 2006 is improper. The Office action is technically considered a Supplemental Examiner's Answer in response to the Reply Brief filed July 10, 2006. Also, the Group Director's signature is missing. See MPEP § 1207.05. Correction is required.

Accordingly, it is ORDERED that the application is returned to the Examiner:

- 1) to vacate the defective Examiner's Answer mailed June 15, 2006;
- 2) to issue a corrected Examiner's Answer which contains the Group Director's signature as required by MPEP § 1207.03;
- 3) to clarify the status of omitted claims 42, 44-46 and 48-49 in the "Grounds of Rejection" section of the corrected Examiner's Answer;
  - 4) to vacate the office action mailed October 17, 2006;
- 5) to issue a corrected Supplemental Examiner's Answer in place of the Office Action of October 17, 2006 properly labeled as such, and obtain the Group Director's signature; and
  - 6) for such further action as may be appropriate.

BOARD OF PATENT APPEALS AND INTERFERENCES

PATRICK I NOI AN

Deputy Chief Appeals Administrator

(571) 272-9797